

REMARKS

Independent Claims 1, 19 and 36 and dependent claim 39 have been amended to limit the peptide measured in the method of the claim to peptide consisting of the specified amino acid sequence. It is believed that none of these amendments constitute new matter and their entry is requested.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 1, 3, 4, 6, 19 and 36-40 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully disagrees and traverses this rejection. As discussed in detail in previous responses in the instant application, the specification provides evidence demonstrating that levels of peptides of SEQ ID NOs: 1 and 4 (the "Peptides") directly correlate with the presence of the magnesium binding defect. Thus, detection of the presence of these peptides provides a method to detect the magnesium binding defect and predict the risk of developing associated disorders, such as preeclampsia.

The Examiner asserts that the specification does not explicitly teach a link between levels of the Peptides and preeclampsia. However, the claims are drawn to a method for assessing the risk of developing preeclampsia, and is limited to occurrence of preeclampsia associated with the magnesium binding defect (the "MgBD"). Applicant urges that the disclosure of the instant specification, specifically the correlation of the presence of the MgBD in individuals that presented with preeclampsia during pregnancy (Example 4), combined with the teachings of the specification that administration of the Peptides to rat models with essential hypertension ameliorated the MgBD, demonstrates that the method actually works, and provides more than a

respectable guess as to the likelihood of its operability. (See, *Rasmussen v. SmithKline Beecham Corp.* (2005))

The examiner has rejected the teaching of the specification that hypertension, diabetes and preeclampsia have a common marker, the presence of the MgBD, citing Page et al. and D'Anna et al. for the disclosure that plasma levels of neurokinin B in patients diagnosed with preeclampsia was significantly increased as compared to normal controls. The Applicant has amended the independent claims to limit the description of the measured peptides to the amino acid sequences of SEQ ID NO. 1 and SEQ ID NO. 4. As such, the levels of the Peptides can not be directly compared to the levels of neurokinin B reported by Page et al. or D'Anna et al. One of reasonable skill in the art would recognize that the levels of degradation products of neurokinin B could either directly or indirectly vary with the levels of the Peptides. Furthermore, the instant specification describes a method for identifying a risk of developing preeclampsia by teaching the correlation between the levels of the Peptides in body fluids with the presence of the MgBD.

Rejections under 35 U.S.C. § 102

The Examiner rejected claims 36 and 37 as being anticipated by Page et al. The amendment of the independent claim 36 (and dependent claims 37, thereby) obviates this rejection and Applicant respectfully requests the withdrawal of same.

Rejections under 35 U.S.C. § 103

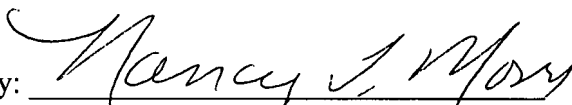
The Examiner has rejected claims 36, 37, 38 and 39 as being unpatentable over Page et al. in view of Janeway et al. The amendment of the independent claim 36 (and dependent claims

37, 38 and 39, thereby) obviates this rejection and Applicant respectfully requests the withdrawal of same.

In summary, the instant specification provides sufficient teaching to enable one skilled in the art to compare and correlate the levels of Peptides with the magnesium binding defect. Direct measurement of the Peptides is within the ordinary level of skill in the art. Furthermore, the specification provides evidence of the biological activity of the Peptides, i.e., that increasing the level of the Peptides increases magnesium binding up to normal levels, and concomitantly ameliorates the magnesium binding defect. Thus, the specification provides a reasonable correlation between detecting the levels of Peptides and identifying individuals having the magnesium binding defect.

In view of the foregoing amendments and remarks, Applicant urges that the instant specification enables the full breadth of the claims and requests that the rejections be withdrawn. If the examiner is of the view that any issue remains unresolved, it is respectfully suggested that Applicant's undersigned attorney may be contacted by telephone at the number set forth below.

Respectfully submitted,

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